DEPARTMENT OF HEALTH HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 14 1999

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Mr. David H. Schubert
Director, Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, MA 02139-1562

Re: Docket Nos. 98P-0752/CP1 and 98N-0056

Dear Mr. Schubert:

This letter responds to your citizen petition dated September 1, 1998, in which you and Ms. Rhonda Buyers of the National Gaucher Foundation request that the Food and Drug Administration (FDA) add imiglucerase to the priority section of the List of Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and concluded that imiglucerase meets the criteria for inclusion on the priority section of the list. Accordingly, your petition is granted. FDA will add imiglucerase to the priority section of the list for the indication long-term enzyme replacement therapy for patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: (a) anemia, (b) thrombocytopenia, (c) bone disease, or (d) hepatomegaly or splenomegaly.

Please be aware that inclusion of a drug on the list does not guarantee that pediatric studies are necessary. Rather, inclusion indicates that gaps exist in the drug's pediatric labeling. Further, inclusion does not guarantee that FDA will issue a Written Request, particularly if adequate pediatric data exist and have been submitted previously to the Agency. We encourage you to file a labeling supplement containing any pediatric data you have.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

98P-0752

PAV1

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code:	98P-0752/PAV 1
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